REMARKS

The applicant provides the following remarks which along with the claims as amended address each of the concerns raised by the examiner.

Cancellation of Claims. The applicant cancels claims 13-15 without prejudice. The applicant does not waive the right to have these claims examined in a subsequent continuing application, if desired.

Section 112 Concerns. The office raised Section 112 concerns with respect to claims 13, 14, 20-22, 24, 28, and 171.

Claims 13 and 14 have been canceled making amendment moot.

The applicant has amended the preamble of claims 21, 22, and 24 to remove "having a predetermined sex".

Claim 15 has been canceled making amendment moot.

Claim 20 has been amended to recite – between any of days 2 to 18 – as suggested by the examiner.

Claim 28 has been amended to recite – a collector – to address the antecedent basis concern.

Claim 1 and 170 -171 have been amended to recite -- inserting a portion of said insemination sample into a female species of said mammal – which addresses the antecedent basis concern with respect to claims 170 and 171.

Section 102 Concerns. The office raised Section 102 concerns with respect to claims 1, 2, 5-15, 19, 25, and 169-171 as anticipated by the Siedel reference entitled "Insemination of Holstein heifers with very low numbers of unfrozen spermatozoa" which consists of an abstract of a single page having no internal reference date other than that date handwritten on the reference by the office of July, 1995 (the "Abstract"). The applicant is still investigating the actual reference date of the abstract and has not been able to identify any other "whole document" to which the office further refers. As such, the applicant specifically traverses the date of the reference and further traverses that a "whole document" other than that forwarded in the official communication exists. If that document exists, the applicant specifically requests that the office forward the entire document which comprises the basis for the enumeration of the various limitations set out in the official communication so that the applicant can review it. As such any amendments made by the applicant are solely for the purposes of expediting the examination and the applicant does not waive any right to broaden the claims in a subsequent continuing application consistent with the applicant's then existing knowledge of the references.

A claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. §2131, MPEP; Verdegall Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. §2131, MPEP; Richardson v. Suzuki Moteor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989). Moreover, even if the conventional technology performs all the functions recited in the claim, the conventional technology cannot anticipate the claim if there is any structural difference. §2114, MPEP; In re Ruskin, 347 F.2d 843 (CCPA 1965); In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999). Moreover, "The elements must be arranged as required by the claim". §2131, MPEP; In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990) (emphasis added).

With respect to the Seidel reference consisting of a single page forwarded by the office, certain limitations attributed to that reference are traversed by the applicant. First, the office indicates that the Seidel reference teaches the limitation that "the insemination occurs no later than 17 hours from establishment of the semen sample" and the limitations that "the

insemination occurs no later than 10 hours from establishment of the semen sample". It is clear from the Seidel reference that "fully extended semen was packed into French straws to deliver. . .insemination doses" and that the "semen was cooled to 5° and used 26-57 h after collection". As such, more than 10 hours or more than 17 hours elapsed from "establishment of the semen sample" when it was packed into French straws.

The limitation of "using a ovulatory pharmaceutical to cause multiple eggs to be produced" is clearly not taught by the Seidel reference . There is no teaching concerning any pharmaceutical that would cause multiple eggs to be produced such as follicle stimulating hormone. It is well known that the pharmaceutical discussed in the Seidel reference serves to synchronize estrus for convenience of insemination but does not superovulate the mammal.

The applicant further traverses the offices assertion the "control" of 2.5 million sperm can be thought of as the "typical dosage". A "control" does not define what is "typical" rather it provides a baseline to compare experimental parameters against. The applicant has defined low dose insemination as being up to "50%" of the "typical" number of sperm cells used for insemination. Specification at page 19, line 9. As such, 2.5 million sperm would be a "low dose" as defined by the applicant.

It is also clear from the Seidel reference that the limitations of "determining the characteristic of a plurality of sperm cells"; "separating the sperm cells according to the determination of sex characteristic"; "establishing a sperm cell source"; "sensing a property of the sperm cells; discriminating between the sperm cells having the desired sex characteristic" or "collecting sperm cells having the desired characteristic" were not performed with respect to any of the sperm cells referred to in the reference itself. The office indicates that this is the case in Item 9 of the communication ("fail to disclose a sheath fluid for the sperm cells").

Moreover, it is clear that the author Seidel, who is a person having greater than ordinary skill in the field, had repeated subsequent failures to impregnate mammals ("none of 10 females

became pregnant") with sorted sperm cells or achieved only 1 pregnancy in seven inseminations or only a single pregnancy in 33 inseminations months after the publication of the Seidel reference. It is clear that at the time the Seidel reference was published the author did not have possession of the an invention for the insemination of mammals with separated sperm cells capable of generating pregnancy rates comparable to semen inseminated mammals and that any general statements concerning insemination with sorted sperm cells is not enabled. See journal article entitled "Artificial Insemination With X- and Y-Bearing Bovine Sperm" published after the priority date of the instant application.

Section 103 Concerns.

A prima facie case of obviousness requires that the combination of references disclose all the limitations of the claimed invention. §2143, MPEP; §2143.03, MPEP; In re Royka, 490 F.2d 981 (CCPA 1974).

Item 9. With respect to claims 16, 17, 20-23, 24, 26, and 165-167, to which the office raised Section 103 concern over Seidel et al (the "Abstract") in view of Adair (The "Adair reference").

First, with respect to the Seidel reference and the Adair reference limitations of a "sheath fluid containing sodium citrate"; a "cushioning the sperm cells; and providing a "citrate collection fluid containing egg yolk" or a "2.9% sodium citrate sheath fluid" are not taught by the combination of the references.

The Adair reference only teaches "diluting solutions" which contain various components. Adair, Col. 3, ll. 14-15. The Adair reference does not indicate that any particular type of "sheath fluid" or "cushioning element" at all. It is well known that you cannot run egg yolk through a flow cytometer and that sheath fluids used until the instant invention were saline solutions. It is

still covers not pure egg yolk

also well known that prior to the instant invention cells were typically collected onto collection surfaces without any cushioning element at all.

The combination of the Seidel reference and the Adair reference do not teach at all any manner of "chemically coordinating a sheath fluid environment for sperm cells which is coordinated with both the pre-sort and post-sort cell fluid environments.

Adair and the Seidel reference in combination do not teach the limitation of claims 20-23 which comprise superovulation of a mammal as discussed above. The office attempts uses the argument of "design choice" to provide the missing limitation. However, where the combination of references such as the Seidel reference and the Adair reference only provide a general approach as to the particular form of the claimed invention or how to achieve it, the invention is not obvious, but only obvious -to-try. In Re O'Farrell, 853 F. 2d 894, 903 (Fed. Cir. 1988). Because superovulated animals are well known to be difficult to inseminate and are typically inseminated with multiple insemination samples to achieve pregnancies, the combination of references does not provide one of ordinary skill in the art a reasonable expectation of successfully making the invention at the time the invention was made. §2143.02, MPEP.

Nor does the combination of references disclose the use of "38 micro-molar content stain" as set out by claim 23.

With respect to claim 16, the combination of references do not disclose the achievement of a single pregnancy with sperm cells which have been separated according to sex type. This is not the claimed "production of an offspring". It is clear from the subsequent failures to achieve pregnancies with sperm cells separated according to sex type, as discussed above, that the combination of the references either do not show possession of the instant invention, or do not

enable a person of ordinary skill in the art to produce the instant invention successfully as required under the rules. §2143.02, MPEP.

Because the required limitations are not disclosed by the combination of references or because the combination of references do not enable or provide the person of ordinary skill in the art the expectation of successfully making the invention at the time the invention was made claims 16, 17, 20-23, 24, 26, and 165-167 as amended are allowable along with any dependent claims thereon.

Items 10 and 11. With regard to claim 18 and claim 168, the office raised a concern that the limitation of "500 sorts per second" or "1200 sorts per second" are unpatentable over the Seidel reference in view of United States Patent No. 5,346,990 to Spaulding ("Spaulding") or unpatentable over the Seidel reference and Adair in view of Spaulding. The applicant has amended claim 18 to recite "greater than 500 sorts per second". This limitation is not disclosed by the combination of references as required under the rules to support a determination of obviousness. §2143, MPEP; §2143.03, MPEP; In re Royka, 490 F.2d 981 (CCPA 1974). Either combination of references does not teach a sort rate of greater than 500 sorts per second or of at least 1,200 sorts per second as asserted by the office. As indicated by the office the Abstract and the Adair reference do not disclose sort rates, and Spaulding does not teach a sort rate greater than 500 sorts per second. In fact, the rates actually obtained by Spaulding were much lower that 500 sorts per second. As can be understood "300,000 cells" required 30 minutes to sort (166 sorts per second). Spaulding at col. 10, l.13.

Still [illegible]

for "enriched" cells

Because the combination of references do not disclose the limitation of "greater than 500 sorts per second", the applicant believes that claim 18 and any claims dependent thereon are

allowable.

Item 12. With regard to claims 28 and 29, the office has raised a concern that the limitations of "avoiding impact of said sperm cells with said collector" and "providing a container having a diameter of at least fifteen millimeters" are unpatentable over the Seidel reference and Adair in view of Figures 2-4 and 6 of United States Patent No. 4,327,177 to Shrimpton (Shrimpton).

The combination of references do not teach the steps of "avoiding impact of sperm cells with a collector" or the step of avoiding impact by "providing a collection container having a diameter of at least 15 millimeters" as required under the rules. §2143, MPEP; §2143.03, MPEP; In re Royka, 490 F.2d 981 (CCPA 1974).

As indicated by the office the Abstract and the Adair reference do not teach the limitations of "avoiding impact of sperm cells in the collector" or "a collection container having a diameter of at least 15 millimeters". Communication at page 7. The applicant specifically traverses the offices assertion that the Shrimpton reference teaches the steps of "avoiding impact of the sperm cells in the collector" or the step of "providing a collection container having a diameter of at least 15 millimeters". As can be understood from Figures 2-4 and 6, Shrimpton does not even teach a flow cytometer. Shrimpton teaches that "a density gradient column results in a suspended state of separation of the sperm according to density". Shrimpton, Col. 9, ll. 23-25. As such, the sperm cells may have no velocity which would necessitate avoiding impact with any container what-so-ever. Moreover, Shrimpton teaches that "gaseous pressure" can "supplement the hydrostatic head serving

to discharge the sperm fractions into the vials". Shrimpton Col. 11, ll. 15-18. However, Shrimpton does not teach or suggest the step of "avoiding impact" with the "vial". Specifically, Shrimpton does not teach step of providing a flow cytometer container having a diameter of "15 milimeters".

Because the combination of references do not teach the elements of claims 28 and 29, claims 28 and 29 along with claims dependent thereon should be allowable.

Item 13. With respect to the offices Section 103 concerns regarding claims 27, 172, and 173 over Siedel et al. (1995) and in view of Siedel (1997). The applicant believes that a prima facie case of obviousness cannot be established because the Siedel (1997) reference is predated by the priority date of the instant application.

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. A method of producing a mammal comprising the steps of:

a. collecting sperm cells from a male of a species of mammal;

b. establishing a sperm cell source which supplies sperm cells to be separated;

c. sensing a sex characteristic of said sperm cells;

d. separating sperm cells based upon said sex characteristic;

[b.] e. establishing an insemination sample [having no more than 10% of the number of said sperm cells relative to a typical insemination sample] having a low number of separated sperm cells capable of fertilizing at least one egg within said female of said species of said mammal at success levels comparable to a typical insemination dosage;

[c.] f. inserting a portion of said insemination sample into a female of said species of said mammal;

[d.] g. fertilizing at least one egg within said female of said species of said mammal [at success levels statistically comparable to a typical insemination dosage, wherein said steps of inserting said insemination sample into a female of said species of said mammal and fertilizing at least one egg within said female of said species of said mammal at success levels statistically comparable to the typical insemination dosage are each accomplished in a field environment]; and

[e.] h. producing an offspring mammal.

2. A method of producing a mammal as described in claim 1 wherein said step of establishing an insemination sample having a low number of separated sperm cells capable of fertilizing at least one egg within said female of said species of said mammal at success levels comparable to a typical insemination dosage comprises [fertilizing at least one egg within said female of said species of said mammal at success levels statistically comparable to a typical insemination dosage comprises the step of fertilizing said at least one egg within said female of said species at] establishing an insemination

sample having a low number of separated sperm cells capable of fertilizing at least one egg within said female of said species at success levels selected from the group consisting of at least 35%, at least 41%, at least 50%, and at least 90%.

5. A method of producing a mammal as described in claim 1 wherein said female of said species of said mammal has uterine horns and wherein said step of inserting a portion of said insemination sample into said female of said species of said mammal comprises the step of inserting said portion of said insemination sample both ipsi- and contra-lateral within the uterine horns of said female of said species of said mammal.

6. A method of producing a mammal as described in claim 1 wherein said female of said species of said mammal has at least one uterine horn and wherein said step of inserting said portion of said insemination sample into said female of said species of said mammal comprises the step of inserting said portion of said insemination sample deep within said uterine horn.

7. A method of producing a mammal as described in claim 5 wherein said step of inserting said portion of said insemination sample into a female of said species of said mammal further comprises the step of inserting said portion of said insemination sample deep within said uterine horns.

8. A method of producing a mammal as described in claim 6 wherein said step of inserting said portion of said insemination sample into a female of said species of said mammal further comprises the step of inserting said portion of said insemination sample within said uterine horn through the use of embryo transfer equipment.

9. A method of producing a mammal as described in claim 7 wherein said step of inserting said portion of said insemination sample into a female of said species of said mammal

further comprises the step of inserting said portion of said insemination sample within said uterine horns through the use of embryo transfer equipment.

10. A method of producing a mammal as described in claim 5 wherein said step of inserting said portion of said insemination sample into a female of said species of said mammal comprises the step of inserting said portion of said insemination sample twelve hours after the time which is generally regarded as optimal for a single insemination.

11. A method of producing a mammal as described in claim 9 [wherein said step of establishing an insemination sample comprises the step of establishing an unfrozen insemination sample,] wherein said step of inserting said portion of said insemination sample into a female species of said mammal occurs not later than about seventeen hours from said step of establishing an insemination sample having a low number of separated sperm cells capable of fertilizing at least one egg within said female of said species of said mammal at success levels comparable to a typical insemination dosage [establishing said insemination sample having no more than 10% of the number of said sperm cells relative to the typical artificial insemination dosage].

12. A method of producing a mammal as described in claim 9 [wherein said step of establishing an insemination sample comprises the step of establishing an unfrozen insemination] wherein said step of inserting said portion of said insemination sample into a female [species] of said species of mammal occurs not later than about ten hours from said step of establishing said insemination sample [having no more than 50% of the number of said sperm cells relative to the typical artificial insemination dosage].

[13. A method of producing a mammal as described in claim 1 further comprising the step of determining a sex characteristic of a plurality of said sperm cells.

14. A method of producing a mammal having a predetermined sex as described in claim 13 further comprising the step of separating said sperm cells according to the determination of said sex characteristic.

15. A method of producing a mammal as described in claim 14 wherein said step of separating said sperm cells according to the determination of their sex characteristic comprises the steps of:

a. establishing a sperm cell source which supplies sperm cells to be separated;

b. sensing a property of said sperm cells;

c. discriminating between said sperm cells having a desired sex characteristic; and

d. collecting said sperm cells having the desired sex characteristic.]

16. A method of producing a mammal as described in claim [15] 1 [wherein said steps of separating said sperm cells according to the determination of their sex characteristic] further [comprises] comprising the steps of:

a. providing a flow cytometer;

b. establishing a sheath fluid for said sperm cells; and

c. collecting said sperm cells having the desired sex characteristic.

17. A method of producing a mammal as described in claim 16 wherein said step of collecting said sperm cells having the desired sex characteristic further comprises the step of cushioning said sperm cells from impact with a collector.

18. A method of producing a mammal as described in claim 16 wherein said step of providing a [sorting] flow cytometer comprises the step of providing a high speed sorting flow cytometer, wherein said high speed sorting flow cytometer [sorts] separates said sperm cells at a rate of [at least] greater than 500 sorts per second.

19. A method of producing a mammal as described in claim 3 [and] further comprising the step of using an ovulatory pharmaceutical to cause multiple eggs to be produced.

20. A method of producing a mammal as described in claim 19 wherein said ovulatory pharmaceutical is injected in half day increments between any of days 2 [and] to 18 of the estrus cycle.

21. A method of producing a mammal [having a predetermined sex] as described in claim 20 wherein said step of using an ovulatory pharmaceutical to cause multiple eggs to be produced comprises the step of injecting a dosage of follicle stimulating hormone.

22. A method of producing a mammal [having a predetermined sex] as described in claim 21 wherein said step of injecting said dosage of follicle stimulating hormone in approximately half day increments comprises a dosage level of 6, 6, 4, 4, 2, 2, 2, and 2 mg between days 9 and 12 inclusive of the estrus cycle and further comprising the step of injecting 25 mg and 12.5 mg of prostaglandin F-2-alpha on the sixth and seventh dosages, respectively, of said follicle stimulating hormone.

23. A method of producing a mammal as described in claim 16 [and wherein said step of determining the sex characteristic of a plurality of said sperm cells and said step of sorting said sperm cells according to the determination of their sex characteristic] further [comprises] comprising the step of staining said sperm cells of [a] said male of said species of mammal with at least about 38 micro-molar [content] concentration of stain.

24. A method of producing a mammal [having a predetermined sex] as described in claim 16 further comprising the step of chemically coordinating a sheath fluid environment for sperm cells which is coordinated with both pre-sort and post-sort sperm cell fluid environments.

25. A method of producing a mammal as described in claim 1, 2, [14, 15,] 16, 17 or 18 wherein collecting sperm cells from a male of a species of mammal comprises collecting said sperm cells from a male of a species selected from the group consisting of bovines, and equines.

26. A method of producing a mammal as described in claim 25 wherein said step of chemically coordinating a sheath fluid to create a sheath fluid environment for said sperm cells which is coordinated with both a pre-sort and a post-sort cell fluid environments comprises the step of establishing a cell source which supplies bovine sperm cells and the step of establishing a sheath fluid which contains about 2.9% sodium citrate.

27. A method of producing a mammal as described in claim 25 wherein said step of chemically coordinating a sheath fluid to create a sheath fluid environment for said cells which is coordinated with both a pre-sort and a post-sort cell fluid environment comprises the step of establishing a cell source which supplies equine sperm cells and the step of establishing a sheath fluid which contains a hepes buffered medium.

28. A method of producing a mammal as described in claim 16 wherein said step of collecting said sperm cells having the desired sex characteristic further comprises the step of avoiding impact of said sperm cells with [said] a collector.

29. A method of producing a mammal as described in claim 28 wherein said step of avoiding impact of said sperm cells with said collector comprises the step of providing a collection container having a diameter of at least fifteen millimeters.

165. A method of producing a mammal as described in claim 28 wherein said step of avoiding impact of said sperm cells with said collector comprises the step of providing a collection container having stream matched physical characteristics.

166. A method of producing a mammal as described in claim 16 wherein said step of collecting said sperm cells having the desired sex characteristic further comprises the step of providing a citrate collection fluid containing about six percent egg yolk prior to commencing said step of collecting.

167. A method of producing a mammal as described in claim 18 further comprises the step of operating said flow cytometer with in the range of about 5 kilohertz to about 50 kilohertz.

168. A method of producing a mammal as described in claim 185 further comprises the step of [sorting] separating said sperm cells at a rate of at least 1200 sorts per second.

169. A method of producing a mammal as described in claim 3 wherein said step of [establishing a insemination sample having a low number of said sperm cells relative to the typical artificial insemination dosage] establishing an insemination sample having a low number of separated sperm cells capable of fertilizing at least one egg within said female of said species of said mammal at success levels comparable to a typical insemination dosage comprises the step of establishing an insemination sample selected from the group consisting of: a bovine insemination sample of no more than one hundred thousand sperm cells, a bovine insemination sample of no more than two hundred fifty thousand sperm cells, a bovine insemination sample of no more than three hundred thousand sperm cells, an equine insemination sample of no more than one million sperm cells, an equine insemination sample of no more than five million sperm cells, an equine insemination sample of no more than ten million sperm cells, and an equine insemination sample of no more than twenty-five million sperm cells.

170. A method of producing a mammal as described in claim 4 wherein said step of inserting [at least] a portion of said insemination sample into a female species of said mammal and said step of fertilizing at least one egg within said female species of said mammal [at success levels statistically comparable to the typical unsexed artificial insemination

dosage] occurs in a field environment [comprises the steps of repetitively inserting a significant number of insemination samples into a significant number of female specie of said mammal in rapid succession and in farm or ranch conditions].

171. A method of producing a mammal as described in claim 14 wherein said step of inserting said portion of said insemination sample [having said low number of said sperm cells] into a female of said species of said mammal comprises inserting a portion of an insemination sample wherein [having a low number of sperm] substantial portion of [which] said separated sperm cells have the desired sex characteristic.

172. A method of producing a mammal as described in claim 189 wherein said step of inserting a portion of an insemination sample [having a low number of sperm, wherein a] wherein a substantial portion of said separated sperm cells have the desired sex characteristic comprises selecting said insemination sample [having a low number of sperm] from a group consisting of [an insemination sample having a low number of sperm, wherein] an insemination sample wherein at least 60 percent of said separated sperm cells have the desired sex characteristic, an insemination sample [having a low number of sperm,] wherein at least 70 percent of said sperm have the desired sex characteristic, an insemination sample [having a low number of sperm,] wherein at least 80 percent of said sperm have the desired sex characteristic, and an insemination sample [having a low number of sperm,] wherein at least 90 percent of said sperm have the desired sex characteristic.

173. A method of producing a mammal as described in claim 190 wherein said step of producing an offspring mammal comprises producing a predetermined sex ratio of fetuses.

CONCLUSION

Based upon the foregoing the applicant believes that this response places this application in condition for allowance and such action is respectfully requested.

The applicant respectfully requests a telephone interview to address any remaining concerns that the examiner may have.

Dated this 6th day of May, 2003.

Respectfully Submitted,
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